II. REMARKS

A. Status of the Claims

Claims 1, 15, 16, 17, 18, 27, and 37 have been amended without prejudice.

New claims 39-56 have been added.

Support for the amendments and new claims can be found, e.g., on page 6, last paragraph, to page 8, last paragraph, of the specification as filed.

Claims 1-56 are pending.

Applicants respectfully submit that no new matter has been added by virtue of these amendments.

B. Claim Rejections- 35 U.S.C. § 103

Claims 1-26 were rejected under 35 U.S.C. § 103(a) over WO 99/32120 to Palermo ("the Palermo publication").

Independent claims 1, 16, 17, 18 all recite in part "a C_{24}/C_{max} ratio of 0.55 to about 0.85." "The term "C_{24}" ... is the plasma concentration of the drug at 24 hours after administration." See page 4, line 12 of the specification as filed. "The term "C_{max}" denotes the maximum plasma concentration obtained during the dosing interval." See page 4, line 11 of the specification as filed.

The Palermo publication does not disclose any specific pharmacokinetic values (i.e., C_{24} and C_{max}) for the dosage forms described therein.

In a recent decision, United States Court of Appeals reconfirmed that, even in view of *KSR International Co. v. Teleflex Inc.*, ---U.S. ----, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007), it "**remains necessary** to show ... some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness ..." See *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1301 (Fed. Cir. 2007).

Relying on this decision of the United States Court of Appeals, a district court has subsequently held that references which do not teach the specific pharmacokinetic parameters do not render these pharmacokinetic parameters obvious. Specifically, the court stated that "just as the absence of the PK [pharmacokinetic] limitations ... was sufficient ... to defeat an anticipation claim; **it is also sufficient here to defeat ... obviousness challenge**". See *Abbott Laboratories v. Sandoz, Inc.*, 2007 WL 4287501 at 28 (N.D.Ill 2007) (emphasis added).

Manual of Patent Examining Procedure states that:

> The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at ___ , 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval).

See MPEP, Section 2142.

Manual of Patent Examining Procedure also states that:

> The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness."

See Id.

Further, the fact that a claimed species may be encompassed by a genus of the cited reference is not sufficient by itself to establish a *prima facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). Some motivation to select the claimed species or subgenus must be taught by the prior art. See e.g., *In re Deuel*, 51 F.3d at 1558-59, 34 USPQ2d at 1215.

Moreover, MPEP states that "... Office personnel **must** articulate ... a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable." See MPEP, section 2143. (emphasis added).

In the present case, the Office has not articulated what in the Palermo publication would have provided a suggestion of the C_{24}/C_{max} ratio recited in the present claims, let alone provided evidence that shows that "the natural result flowing ..." from the Palermo publication would result in the specific C_{24}/C_{max} ratio recited in the present claims. See *Abbott Laboratories v. Sandoz, Inc.*, 2007 WL 4287501 at 28 (N.D.Ill 2007).

The Office has also failed to provide a finding that one of ordinary skill in the art would have recognized that the results of the combination (i.e., the specific C_{24}/C_{max} ratio) were predictable.

Accordingly, Applicants submit that the prima facie case of obviousness has not been established in the present case. See MPEP, Section 2142 and 2143.

Applicants respectfully reiterate that the Palermo publication does not describe the specific PK limitations and the ratio of these limitations (i.e., C_{24}/C_{max} ratios recited in the present claims). The Palermo publication also does not describe any *in vivo* dissolution data. Furthermore, the Palermo publication does not expressly offer the PK ("pharmacokinetic) profile of the formulations described therein.

Accordingly, Applicants submit that, at the very least, the Palermo publication does not render obvious the specific C_{24}/C_{max} ratio recited in the present claims. See, e.g., Abbott Laboratories v. Sandoz, Inc., 2007 WL 4287501 at 28 (N.D.Ill 2007).

For the same reasons, Applicants submit that the Palermo publication does not render obvious "a rate of absorption during the time period from T_{max} to about 24 hours after oral administration of the dosage form which is from about 45% to about 85% of the rate of elimination during the same time period" as recited in claim 15. See Id.

With further regard to new claims 39, 41, 43, 45, and 47, Applicants submit that the Palermo publication would have suggested to one skilled in the art a dosage form wherein the active agent "is selected from the group consisting of hydrocodone, a non-opioid drug, their mixtures and pharmaceutically acceptable salts thereof," because the dosage form in accordance with the Palermo publication would necessarily include an opioid antagonist.

For the foregoing reasons, withdrawal of the obviousness rejection over the Palermo publication is respectfully requested.

Claims 27-38 were rejected under 35 U.S.C. § 103(a) over the Palermo publication in view of U.S. Patent No. 4,844,907 to Elger et al. ("The Elger patent"). The Elger patent was relied upon for the teaching of "the composition in the form of a multi-phase, layered tablet, especially bi-layered tablet." See Office Action, page 7.

Independent claims 27, 36, 37, and 38 recite in part an osmotic dosage form comprising a bilayer **core** comprising "a displacement layer comprising **osmopolymer**" and "a **semipermeable wall** ... surrounding the bi-layer core having a **passageway** disposed therein."

Applicants submit that the combination of the cited references does not describe an osmotic dosage form as recited in independent claims 27, 36, 37, and 38.

Applicants further submit that the combination of the cited references does not render obvious the specific C_{24}/C_{max} ratios recited in the present claims, for the reasons set forth above with regard to the obviousness rejection over the Palermo publication.

With further regard to new claims 49, 51, 53, and 55, Applicants submit that the Palermo publication would have suggested to one skilled in the art a dosage form wherein the active agent "is selected from the group consisting of hydrocodone, a non-opioid drug, their mixtures and pharmaceutically acceptable salts thereof" as recited in the claims, because the dosage form in accordance with the Palermo publication would necessarily include an opioid antagonist.

For the foregoing reasons, withdrawal of the obviousness rejection is respectfully requested.

III. CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully requested to contact the undersigned at the telephone number provided below in the event that a telephonic interview will advance the prosecution of the application.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____
Oleg Ioselevich
Reg. No. 56,963

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940